104TH CONGRESS 1ST SESSION

H. R. 435

To establish a code of fair information practices for health information, to amend section 552a of title 5, United States Code, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 9, 1995

Mr. Condit introduced the following bill; which was referred to the Committee on Commerce and, in addition, to the Committees on Government Reform and Oversight and the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To establish a code of fair information practices for health information, to amend section 552a of title 5, United States Code, and for other purposes.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.
- 4 (a) SHORT TITLE.—This Act may be cited as the
- 5 "Fair Health Information Practices Act of 1995".
- 6 (b) Table of Contents.—The table of contents for
- 7 this Act is as follows:
 - Sec. 1. Short title; table of contents.
 - Sec. 2. Findings and purposes.

Sec. 3. Definitions.

TITLE I—FAIR HEALTH INFORMATION PRACTICES

Subtitle A—Duties of Health Information Trustees

- Sec. 101. Inspection of protected health information.
- Sec. 102. Amendment of protected health information.
- Sec. 103. Notice of information practices.
- Sec. 104. Accounting for disclosures.
- Sec. 105. Security.

Subtitle B-Use and Disclosure of Protected Health Information

- Sec. 111. General limitations on use and disclosure.
- Sec. 112. Authorizations for disclosure of protected health information.
- Sec. 113. Treatment, payment, and oversight.
- Sec. 114. Next of kin and directory information.
- Sec. 115. Public health.
- Sec. 116. Health research.
- Sec. 117. Emergency circumstances.
- Sec. 118. Judicial and administrative purposes.
- Sec. 119. Law enforcement.
- Sec. 120. Subpoenas, warrants, and search warrants.
- Sec. 121. Health information service organizations.

Subtitle C—Access Procedures and Challenge Rights

- Sec. 131. Access procedures for law enforcement subpoenas, warrants, and search warrants.
- Sec. 132. Challenge procedures for law enforcement subpoenas.
- Sec. 133. Access and challenge procedures for other subpoenas.
- Sec. 134. Construction of subtitle; suspension of statute of limitations.
- Sec. 135. Responsibilities of Secretary.

Subtitle D-Miscellaneous Provisions

- Sec. 141. Payment card and electronic payment transactions.
- Sec. 142. Access to protected health information outside of the United States.
- Sec. 143. Standards for electronic documents and communications.
- Sec. 144. Duties and authorities of affiliated persons.
- Sec. 145. Agents and attorneys.
- Sec. 146. Minors.
- Sec. 147. Maintenance of certain protected health information.

Subtitle E-Enforcement

- Sec. 151. Civil actions.
- Sec. 152. Civil money penalties.
- Sec. 153. Alternative dispute resolution.
- Sec. 154. Amendments to criminal law.

TITLE II—AMENDMENTS TO TITLE 5, UNITED STATES CODE

Sec. 201. Amendments to title 5, United States Code.

TITLE III—REGULATIONS, RESEARCH, AND EDUCATION; EFFECTIVE DATES; APPLICABILITY; AND RELATIONSHIP TO OTHER LAWS

Sec. 301. Regulations; research and education.

Sec. 302. Effective dates.

Sec. 303. Applicability.

Sec. 304. Relationship to other laws.

1 SEC. 2. FINDINGS AND PURPOSES.

- 2 (a) FINDINGS.—The Congress finds as follows:
 - (1) The right to privacy is a personal and fundamental right protected by the Constitution of the United States.
 - (2) The improper use or disclosure of personally identifiable health information about an individual may cause significant harm to the interests of the individual in privacy and health care, and may unfairly affect the ability of the individual to obtain employment, education, insurance, credit, and other necessities.
 - (3) Current legal protections for health information vary from State to State and are inadequate to meet the need for fair information practices standards.
 - (4) The movement of individuals and health information across State lines, access to and exchange of health information from automated data banks and networks, and the emergence of multistate health care providers and payors create a compelling need for uniform Federal law, rules, and procedures

- governing the use, maintenance, and disclosure of health information.
 - (5) Uniform rules governing the use, maintenance, and disclosure of health information are an essential part of health care reform, are necessary to support the computerization of health information, and can reduce the cost of providing health services by making the necessary transfer of health information more efficient.
 - (6) An individual needs access to health information about the individual as a matter of fairness, to enable the individual to make informed decisions about health care, and to correct inaccurate or incomplete information.
- 15 (b) PURPOSES.—The purposes of this Act are as 16 follows:
 - (1) To define the rights of an individual with respect to health information about the individual that is created or maintained as part of the health treatment and payment process.
 - (2) To define the rights and responsibilities of a person who creates or maintains individually identifiable health information that originates or is used in the health treatment or payment process.

1	(3) To establish effective mechanisms to enforce
2	the rights and responsibilities defined in this Act.
3	SEC. 3. DEFINITIONS.
4	(a) Definitions Relating to Protected
5	HEALTH INFORMATION.—For purposes of this Act:
6	(1) DISCLOSE.—The term "disclose", when
7	used with respect to protected health information
8	that is held by a health information trustee, means
9	to provide access to the information, but only if such
10	access is provided by the trustee to a person other
11	than—
12	(A) the trustee or an officer or employee of
13	the trustee;
14	(B) an affiliated person of the trustee; or
15	(C) a protected individual who is a subject
16	of the information.
17	(2) DISCLOSURE.—The term "disclosure"
18	means the act or an instance of disclosing.
19	(3) PROTECTED HEALTH INFORMATION.—The
20	term "protected health information" means any in-
21	formation, whether oral or recorded in any form or
22	medium—
23	(A) that is created or received in a State
24	by—
25	(i) a health care provider;

1	(ii) a health benefit plan sponsor;
2	(iii) a health oversight agency;
3	(iv) a health information service orga-
4	nization; or
5	(v) a public health authority;
6	(B) that relates in any way to the past,
7	present, or future physical or mental health or
8	condition or functional status of a protected in-
9	dividual, the provision of health care to a pro-
10	tected individual, or payment for the provision
11	of health care to a protected individual; and
12	(C) that—
13	(i) identifies the individual; or
14	(ii) with respect to which there is a
15	reasonable basis to believe that the infor-
16	mation can be used to identify the individ-
17	ual.
18	(4) Protected individual.—The term "pro-
19	tected individual" means an individual who, with re-
20	spect to a date—
21	(A) is living on the date; or
22	(B) has died within the 2-year period end-
23	ing on the date.

1	(5) USE.—The term "use", when used with re-
2	spect to protected health information that is held by
3	a health information trustee, means—
4	(A) to use, or provide access to, the infor-
5	mation in any manner that does not constitute
6	a disclosure; or
7	(B) any act or instance of using, or provid-
8	ing access, described in subparagraph (A).
9	(b) Definitions Relating to Health Informa-
10	TION TRUSTEES.—For purposes of this Act:
11	(1) Carrier.—The term "carrier" means a li-
12	censed insurance company, a hospital or medical
13	service corporation (including an existing Blue Cross
14	or Blue Shield organization, within the meaning of
15	section $833(c)(2)$ of the Internal Revenue Code of
16	1986), a health maintenance organization, or other
17	entity licensed or certified by a State to provide
18	health insurance or health benefits.
19	(2) Health benefit plan.—The term
20	"health benefit plan" means—
21	(A) any contract of health insurance, in-
22	cluding any hospital or medical service policy or
23	certificate, hospital or medical service plan con-
24	tract, or health maintenance organization group
25	contract, that is provided by a carrier; and

- 1 (B) an employee welfare benefit plan or 2 other arrangement insofar as the plan or ar-3 rangement provides health benefits and is fund-4 ed in a manner other than through the pur-5 chase of one or more policies or contracts de-6 scribed in subparagraph (A).
 - (3) Health benefit plan sponsor" means a person who, with respect to a specific item of protected health information, receives, creates, uses, maintains, or discloses the information while acting in whole or in part in the capacity of—
 - (A) a carrier or other person providing a health benefit plan, including any public entity that provides payments for health care items and services under a health benefit plan that are equivalent to payments provided by a private person under such a plan; or
 - (B) an officer or employee of a person described in subparagraph (A).
 - (4) HEALTH CARE PROVIDER.—The term "health care provider" means a person who, with respect to a specific item of protected health information, receives, creates, uses, maintains, or discloses

1	the information while acting in whole or in part in
2	the capacity of—
3	(A) a person who is licensed, certified, reg-
4	istered, or otherwise authorized by law to pro-
5	vide an item or service that constitutes health
6	care in the ordinary course of business or prac-
7	tice of a profession;
8	(B) a Federal or State program that di-
9	rectly provides items or services that constitute
10	health care to beneficiaries; or
11	(C) an officer or employee of a person de-
12	scribed in subparagraph (A) or (B).
13	(5) Health information service organiza-
14	TION.—The term "health information service organi-
15	zation" means a person who, with respect to a spe-
16	cific item of protected health information, receives,
17	creates, uses, maintains, or discloses the information
18	while acting in whole or in part in the capacity of—
19	(A) a person, other than an affiliated per-
20	son, who performs specific functions for which
21	the Secretary has authorized (by means of a
22	designation or certification) the person to re-
23	ceive access to specific health care data in elec-
24	tronic or magnetic form; or

1	(B) an officer or employee of a person de-
2	scribed in subparagraph (A).
3	(6) Health information trustee.—The
4	term "health information trustee" means—
5	(A) a health care provider;
6	(B) a health information service organiza-
7	tion;
8	(C) a health oversight agency;
9	(D) a health benefit plan sponsor;
10	(E) a public health authority;
11	(F) a health researcher;
12	(G) a person who, with respect to a spe-
13	cific item of protected health information, is not
14	described in subparagraphs (A) through (F) but
15	receives the information—
16	(i) pursuant to—
17	(I) section 117 (relating to emer-
18	gency circumstances);
19	(II) section 118 (relating to judi-
20	cial and administrative purposes);
21	(III) section 119 (relating to law
22	enforcement); or
23	(IV) section 120 (relating to sub-
24	poenas, warrants, and search war-
25	rants); or

1	(ii) while acting in whole or in part in
2	the capacity of an officer or employee of a
3	person described in clause (i).
4	(7) Health oversight agency.—The term
5	"health oversight agency" means a person who, with
6	respect to a specific item of protected health infor-
7	mation, receives, creates, uses, maintains, or dis-
8	closes the information while acting in whole or in
9	part in the capacity of—
10	(A) a person who performs or oversees the
11	performance of an assessment, evaluation, de-
12	termination, or investigation relating to the li-
13	censing, accreditation, or certification of health
14	care providers;
15	(B) a person who—
16	(i) performs or oversees the perform-
17	ance of an audit, assessment, evaluation,
18	determination, or investigation relating to
19	the effectiveness of, compliance with, or
20	applicability of, legal, fiscal, medical, or
21	scientific standards or aspects of perform-
22	ance related to the delivery of, or payment
23	for, health care; and
24	(ii) is a public agency, acting on be-
25	half of a public agency, acting pursuant to

1	a requirement of a public agency, or carry-
2	ing out activities under a State or Federal
3	statute regulating the assessment, evalua-
4	tion, determination, or investigation; or
5	(C) an officer or employee of a person de-
6	scribed in subparagraph (A) or (B).
7	(8) Health researcher.—The term "health
8	researcher" means a person who, with respect to a
9	specific item of protected health information, re-
10	ceives the information—
11	(A) pursuant to section 116 (relating to
12	health research); or
13	(B) while acting in whole or in part in the
14	capacity of an officer or employee of a person
15	described in subparagraph (A).
16	(9) Public Health Authority.—The term
17	"public health authority" means a person who, with
18	respect to a specific item of protected health infor-
19	mation, receives, creates, uses, maintains, or dis-
20	closes the information while acting in whole or in
21	part in the capacity of—
22	(A) an authority of the United States, a
23	State, or a political subdivision of a State that
24	is responsible for public health matters:

1	(B) a person acting under the direction of
2	such an authority; or
3	(C) an officer or employee of a person de-
4	scribed in subparagraph (A) or (B).
5	(c) Other Definitions.—For purposes of this Act:
6	(1) Affiliated person.—The term "affiliated
7	person'' means a person who—
8	(A) is not a health information trustee;
9	(B) is a contractor, subcontractor, associ-
10	ate, or subsidiary of a person who is a health
11	information trustee; and
12	(C) pursuant to an agreement or other re-
13	lationship with such trustee, receives, creates,
14	uses, maintains, or discloses protected health
15	information.
16	(2) Approved Health Research Project.—
17	The term "approved health research project" means
18	a biomedical, epidemiological, or health services re-
19	search or statistics project, or a research project on
20	behavioral and social factors affecting health, that
21	has been approved by a certified institutional review
22	board.
23	(3) Certified institutional review
24	BOARD.—The term "certified institutional review
25	hoard" means a hoard—

1	(A) established by an entity to review re-
2	search involving protected health information
3	and the rights of protected individuals con-
4	ducted at or supported by the entity;
5	(B) established in accordance with regula-
6	tions of the Secretary under section $116(d)(1)$;
7	and
8	(C) certified by the Secretary under section
9	116(d)(2).
10	(4) HEALTH CARE.—The term "health care"—
11	(A) means—
12	(i) any preventive, diagnostic, thera-
13	peutic, rehabilitative, maintenance, or pal-
14	liative care, counseling, service, or proce-
15	dure—
16	(I) with respect to the physical or
17	mental condition, or functional status,
18	of an individual; or
19	(II) affecting the structure or
20	function of the human body or any
21	part of the human body, including
22	banking of blood, sperm, organs, or
23	any other tissue; or
24	(ii) any sale or dispensing of a drug,
25	device, equipment, or other item to an indi-

1	vidual, or for the use of an individual, pur-
2	suant to a prescription; but
3	(B) does not include any item or service
4	that is not furnished for the purpose of main-
5	taining or improving the health of an individual
6	(5) Law enforcement inquiry.—The term
7	"law enforcement inquiry" means a lawful investiga-
8	tion or official proceeding inquiring into a violation
9	of, or failure to comply with, any criminal or civil
10	statute or any regulation, rule, or order issued pur-
11	suant to such a statute.
12	(6) Person.—The term "person" includes an
13	authority of the United States, a State, or a political
14	subdivision of a State.
15	(7) Secretary.—The term "Secretary" means
16	the Secretary of Health and Human Services.
17	(8) State.—The term "State" includes the
18	District of Columbia, Puerto Rico, the Virgin Is-
19	lands, Guam, American Samoa, and the Northern

Mariana Islands.

1	TITLE I—FAIR HEALTH
2	INFORMATION PRACTICES
3	Subtitle A—Duties of Health
4	Information Trustees
5	SEC. 101. INSPECTION OF PROTECTED HEALTH INFORMA-
6	TION.
7	(a) IN GENERAL.—Except as provided in subsection
8	(b), a health information trustee described in subsection
9	(g)—
10	(1) shall permit a protected individual to in-
11	spect any protected health information about the in-
12	dividual that the trustee maintains, any accounting
13	with respect to such information required under sec-
14	tion 104, and any copy of an authorization required
15	under section 112 that pertains to such information;
16	(2) shall provide the protected individual with a
17	copy of the information upon request by the individ-
18	ual and subject to any conditions imposed by the
19	trustee under subsection (d);
20	(3) shall permit a person who has been des-
21	ignated in writing by the protected individual to in-
22	spect the information on behalf of the individual or
23	to accompany the individual during the inspection;
24	and

- 1 (4) may offer to explain or interpret informa-2 tion that is inspected or copied under this sub-3 section.
- (b) EXCEPTIONS.—A health information trustee is not required by this section to permit inspection or copying of protected health information by a protected individual if any of the following conditions apply:
 - (1) Mental Health treatment notes.—

 The information consists of psychiatric, psychological, or mental health treatment notes about the individual, the trustee determines in the exercise of reasonable professional judgment that inspection or copying of the notes would cause sufficient harm to the protected individual so as to outweigh the desirability of permitting access, and the trustee does not disclose the notes to any person not directly engaged in treating the individual, except with the authorization of the individual or under compulsion of law.
 - (2) Information about others.—The information relates to an individual, other than the protected individual or a health care provider, and the trustee determines in the exercise of reasonable professional judgment that inspection or copying of the information would cause sufficient harm to one or

both of the individuals so as to outweigh the desir-1 2 ability of permitting access. 3 (3) Endangerment to life or safety.—Inspection or copying of the information could reasonably be expected to endanger the life or physical 5 6 safety of an individual. 7 (4) CONFIDENTIAL SOURCE.—The information identifies or could reasonably lead to the identifica-8 tion of an individual (other than a health care pro-9 vider) who provided information under a promise of 10 11 confidentiality to a health care provider concerning 12 a protected individual who is a subject of the infor-13 mation. (5) ADMINISTRATIVE PURPOSES.—The informa-14 15 tion— 16 (A) is used by the trustee solely for admin-17 istrative purposes and not in the provision of 18 health care to a protected individual who is a 19 subject of the information; and 20 (B) is not disclosed by the trustee to any 21 person. 22 (6) DUPLICATIVE INFORMATION.—The information duplicates information available for inspection 23

24

under subsection (a).

1	(7) Information compiled in anticipation
2	OF LITIGATION.—The information is compiled prin-
3	cipally—
4	(A) in anticipation of a civil, criminal, or
5	administrative action or proceeding; or
6	(B) for use in such an action or proceed-
7	ing.
8	(c) Inspection and Copying of Segregable Por-
9	TION.—A health information trustee shall permit inspec-
10	tion and copying under subsection (a) of any reasonably
11	segregable portion of a record after deletion of any portion
12	that is exempt under subsection (b).
13	(d) Conditions.—A health information trustee
14	may—
15	(1) require a written request for the inspection
16	and copying of protected health information under
17	this section; and
18	(2) charge a reasonable cost-based fee for—
19	(A) permitting inspection of information
20	under this section; and
21	(B) providing a copy of protected health
22	information under this section.
23	(e) Statement of Reasons for Denial.—If a
24	health information trustee denies in whole or in part a
25	request for inspection or copying under this section, the

- 1 trustee shall provide the protected individual who made
- 2 the request with a written statement of the reasons for
- 3 the denial.
- 4 (f) Deadline.—A health information trustee shall
- 5 comply with or deny a request for inspection or copying
- 6 of protected health information under this section within
- 7 the 30-day period beginning on the date the trustee re-
- 8 ceives the request.
- 9 (g) APPLICABILITY.—This section applies to a health
- 10 information trustee who is—
- 11 (1) a health benefit plan sponsor;
- 12 (2) a health care provider;
- 13 (3) a health information service organization;
- 14 (4) a health oversight agency; or
- 15 (5) a public health authority.
- 16 SEC. 102. AMENDMENT OF PROTECTED HEALTH INFORMA-
- 17 TION.
- 18 (a) IN GENERAL.—A health information trustee de-
- 19 scribed in subsection (f) shall, within the 45-day period
- 20 beginning on the date the trustee receives from a protected
- 21 individual about whom the trustee maintains protected
- 22 health information a written request that the trustee cor-
- 23 rect or amend the information, complete the duties de-
- 24 scribed in one of the following paragraphs:

1	(1) Correction or amendment and notifi-
2	CATION.—The trustee shall—
3	(A) make the correction or amendment re-
4	quested;
5	(B) inform the protected individual of the
6	amendment or correction that has been made;
7	(C) make reasonable efforts to inform any
8	person who is identified by the protected indi-
9	vidual, who is not an employee of the trustee,
10	and to whom the uncorrected or unamended
11	portion of the information was previously dis-
12	closed of the correction or amendment that has
13	been made; and
14	(D) at the request of the individual, make
15	reasonable efforts to inform any known source
16	of the uncorrected or unamended portion of the
17	information about the correction or amendment
18	that has been made.
19	(2) Reasons for refusal and review pro-
20	CEDURES.—The trustee shall inform the protected
21	individual of—
22	(A) the reasons for the refusal of the trust-
23	ee to make the correction or amendment;
24	(B) any procedures for further review of
25	the refusal; and

- 1 (C) the individual's right to file with the 2 trustee a concise statement setting forth the re-3 quested correction or amendment and the indi-4 vidual's reasons for disagreeing with the refusal 5 of the trustee.
- 6 (b) STANDARDS FOR CORRECTION OR AMEND7 MENT.—A trustee shall correct or amend protected health
 8 information in accordance with a request made under sub9 section (a) if the trustee determines that the information
 10 is not accurate, relevant, timely, or complete for the pur11 poses for which the information may be used or disclosed
 12 by the trustee.
- 13 (c) STATEMENT OF DISAGREEMENT.—After a pro-14 tected individual has filed a statement of disagreement 15 under subsection (a)(2)(C), the trustee, in any subsequent 16 disclosure of the disputed portion of the information, shall 17 include a copy of the individual's statement and may in-18 clude a concise statement of the trustee's reasons for not 19 making the requested correction or amendment.
- 20 (d) Construction.—This section may not be con-21 strued to require a health information trustee to conduct 22 a hearing or proceeding concerning a request for a correc-23 tion or amendment to protected health information the 24 trustee maintains.

1	(e) CORRECTION.—For purposes of subsection (a), a
2	correction is deemed to have been made to protected
3	health information when—
4	(1) information that is not timely, accurate, rel-
5	evant, or complete is clearly marked as incorrect; or
6	(2) supplementary correct information is made
7	part of the information and adequately cross-ref-
8	erenced.
9	(f) APPLICABILITY.—This section applies to a health
10	information trustee who is—
11	(1) a health benefit plan sponsor;
12	(2) a health care provider;
13	(3) a health information service organization;
14	(4) a health oversight agency; or
15	(5) a public health authority.
16	SEC. 103. NOTICE OF INFORMATION PRACTICES.
17	(a) PREPARATION OF NOTICE.—A health information
18	trustee described in subsection (d) shall prepare a written
19	notice of information practices describing the following:
20	(1) The rights under this Act of a protected in-
21	dividual who is the subject of protected health infor-
22	mation, including the right to inspect and copy such
23	information and the right to seek amendments to
24	such information, and the procedures for authorizing

1	disclosures of protected health information and for
2	revoking such authorizations.
3	(2) The procedures established by the trustee
4	for the exercise of such rights.
5	(3) The uses and disclosures of protected health
6	information that are authorized under this Act.
7	(b) DISSEMINATION OF NOTICE.—A health informa-
8	tion trustee—
9	(1) shall, upon request, provide any person with
10	a copy of the trustee's notice of information prac-
11	tices (described in subsection (a)); and
12	(2) shall make reasonable efforts to inform per-
13	sons in a clear and conspicuous manner of the exist-
14	ence and availability of such notice.
15	(c) Model Notices.—Not later than July 1, 1996,
16	the Secretary, after notice and opportunity for public com-
17	ment, shall develop and disseminate model notices of infor-
18	mation practices for use by health information trustees
19	under this section.
20	(d) APPLICABILITY.—This section applies to a health
21	information trustee who is—
22	(1) a health benefit plan sponsor;
23	(2) a health care provider;
24	(3) a health information service organization; or
25	(4) a health oversight agency.

SEC. 104. ACCOUNTING FOR DISCLOSURES.

- 2 (a) IN GENERAL.—Except as provided in subsection
- 3 (b) and section 114, each health information trustee shall
- 4 create and maintain, with respect to any protected health
- 5 information the trustee discloses, a record of—
- 6 (1) the date and purpose of the disclosure;
- 7 (2) the name of the person to whom the disclo-
- 8 sure was made;
- 9 (3) the address of the person to whom the dis-10 closure was made or the location to which the disclo-
- sure was made; and
- 12 (4) where practicable, a description of the infor-
- mation disclosed.
- 14 (b) REGULATIONS.—Not later than July 1, 1996, the
- 15 Secretary shall promulgate regulations that exempt a
- 16 health information trustee from maintaining a record
- 17 under subsection (a) with respect protected health infor-
- 18 mation disclosed by the trustee for purposes of peer
- 19 review, licensing, certification, accreditation, and similar
- 20 activities.
- 21 SEC. 105. SECURITY.
- 22 (a) IN GENERAL.—Each health information trustee
- 23 who receives or creates protected health information that
- 24 is subject to this Act shall maintain reasonable and appro-
- 25 priate administrative, technical, and physical safeguards—

1	(1) to ensure the integrity and confidentiality of
2	the information;
3	(2) to protect against any reasonably antici-
4	pated—
5	(A) threats or hazards to the security or
6	integrity of the information; and
7	(B) unauthorized uses or disclosures of the
8	information; and
9	(3) otherwise ensure compliance with this Act
10	by the trustee and the officers and employees of the
11	trustee.
12	(b) Guidelines.—Not later than July 1, 1996, the
13	Secretary, after notice and opportunity for public com-
14	ment, shall develop and disseminate guidelines for the im-
15	plementation of this section. The guidelines shall take into
16	account—
17	(1) the technical capabilities of record systems
18	used to maintain protected health information;
19	(2) the costs of security measures;
20	(3) the need for training persons who have ac-
21	cess to protected health information; and
22	(4) the value of audit trails in computerized
23	record systems.

1	Subtitle B—Use and Disclosure of
2	Protected Health Information
3	SEC. 111. GENERAL LIMITATIONS ON USE AND DISCLO-
4	SURE.
5	(a) Use.—Except as otherwise provided under this
6	Act, a health information trustee may use protected health
7	information only for a purpose—
8	(1) that is compatible with and directly related
9	to the purpose for which the information—
10	(A) was collected; or
11	(B) was received by the trustee; or
12	(2) for which the trustee is authorized to dis-
13	close the information under this Act.
14	(b) DISCLOSURE.—A health information trustee may
15	disclose protected health information only as authorized
16	under this Act.
17	(c) Scope of Uses and Disclosures.—
18	(1) In general.—A use or disclosure of pro-
19	tected health information by a health information
20	trustee shall be limited, when practicable, to the
21	minimum amount of information necessary to ac-
22	complish the purpose for which the information is
23	used or disclosed.
24	(2) Guidelines.—Not later than July 1, 1996,
25	the Secretary, after notice and opportunity for pub-

- lic comment, shall issue guidelines to implement
- 2 paragraph (1), which shall take into account the
- 3 technical capabilities of the record systems used to
- 4 maintain protected health information and the costs
- 5 of limiting use and disclosure.
- 6 (d) Identification of Disclosed Information
- 7 AS PROTECTED INFORMATION.—Except with respect to
- 8 protected health information that is disclosed under sec-
- 9 tion 114 (relating to next of kin and directory informa-
- 10 tion), a health information trustee may disclose protected
- 11 health information only if the recipient has been notified
- 12 that the information is protected health information that
- 13 is subject to this Act.
- 14 (e) AGREEMENT TO LIMIT USE OR DISCLOSURE.—
- 15 A health information trustee who receives protected health
- 16 information from any person pursuant to a written agree-
- 17 ment to restrict use or disclosure of the information to
- 18 a greater extent than otherwise would be required under
- 19 this Act shall comply with the terms of the agreement,
- 20 except where use or disclosure of the information in viola-
- 21 tion of the agreement is required by law. A trustee who
- 22 fails to comply with the preceding sentence shall be subject
- 23 to section 151 (relating to civil actions) with respect to
- 24 such failure.

1	(f) No General Requirement to Disclose.—
2	Nothing in this Act shall be construed to require a health
3	information trustee to disclose protected health informa-
4	tion not otherwise required to be disclosed by law.
5	SEC. 112. AUTHORIZATIONS FOR DISCLOSURE OF PRO-
6	TECTED HEALTH INFORMATION.
7	(a) WRITTEN AUTHORIZATIONS.—A health informa-
8	tion trustee, other than a health information service orga-
9	nization, may disclose protected health information pursu-
10	ant to an authorization executed by the protected individ-
11	ual who is the subject of the information, if each of the
12	following requirements is satisfied:
13	(1) Writing.—The authorization is in writing,
14	signed by the individual, and dated on the date of
15	such signature.
16	(2) SEPARATE FORM.—The authorization is not
17	on a form used to authorize or facilitate the provi-
18	sion of, or payment for, health care.
19	(3) Trustee described.—The trustee is spe-
20	cifically named or generically described in the au-
21	thorization as authorized to disclose such informa-
22	tion.
23	(4) Recipient described.—The person to
24	whom the information is to be disclosed is specifi-
25	cally named or generically described in the author-

- ization as a person to whom such information may be disclosed.
- (5) STATEMENT OF INTENDED USES AND DIS-CLOSURES RECEIVED.—The authorization contains an acknowledgment that the individual has received a statement described in subsection (b) from such person.
 - (6) Information described.—The information to be disclosed is described in the authorization.
 - (7) AUTHORIZATION TIMELY RECEIVED.—The authorization is received by the trustee during a period described in subsection (c)(1).
- 13 (8) DISCLOSURE TIMELY MADE.—The disclo-14 sure occurs during a period described in subsection 15 (c)(2).
- 16 (b) STATEMENT OF INTENDED USES AND DISCLO-17 SURES.—
 - (1) IN GENERAL.—A person who wishes to receive from a health information trustee protected health information about a protected individual pursuant to an authorization executed by the individual shall supply the individual, in writing and on a form that is distinct from the authorization, with a statement of the uses for which the person intends the information and the disclosures the person intends

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1	to make of the information. Such statement shall be
2	supplied before the authorization is executed.
3	(2) Enforcement.—If the person uses or dis-
4	closes the information in a manner that is inconsist-
5	ent with such statement, the person shall be subject
6	to section 151 (relating to civil actions) with respect
7	to such failure, except where such use or disclosure
8	is required by law.
9	(3) Model Statements.—Not later than July
10	1, 1996, the Secretary, after notice and opportunity
11	for public comment, shall develop and disseminate
12	model statements of intended uses and disclosures of
13	the type described in paragraph (1).
14	(c) Time Limitations on Authorizations.—
15	(1) RECEIPT BY TRUSTEE.—For purposes of
16	subsection (a)(7), an authorization is timely received
17	if it is received by the trustee during—
18	(A) the 1-year period beginning on the
19	date that the authorization is signed under sub-
20	section (a)(1), if the authorization permits the
21	disclosure of protected health information to-
22	(i) a health benefit plan sponsor;
23	(ii) a health care provider;
24	(iii) a health oversight agency;
25	(iv) a public health authority;

1	(v) a health researcher; or
2	(vi) a person who provides counseling
3	or social services to individuals; or
4	(B) the 30-day period beginning on the
5	date that the authorization is signed under sub-
6	section (a)(1), if the authorization permits the
7	disclosure of protected health information to a
8	person other than a person described in sub-
9	paragraph (A).
10	(2) Disclosure by trustee.—For purposes
11	of subsection (a)(8), a disclosure is timely made if
12	it occurs before—
13	(A) the date or event (if any) specified in
14	the authorization upon which the authorization
15	expires; and
16	(B) the expiration of the 6-month period
17	beginning on the date the trustee receives the
18	authorization.
19	(d) REVOCATION OR AMENDMENT OF AUTHORIZA-
20	TION.—
21	(1) IN GENERAL.—A protected individual in
22	writing may revoke or amend an authorization de-
23	scribed in subsection (a), in whole or in part, at any
24	time, except insofar as—

1	(A) disclosure of protected health informa-
2	tion has been authorized to permit validation of
3	expenditures based on health condition by a
4	government authority; or
5	(B) action has been taken in reliance on
6	the authorization.
7	(2) Notice of Revocation.—A health infor-
8	mation trustee who discloses protected health infor-
9	mation in reliance on an authorization that has been
10	revoked shall not be subject to any liability or pen-
11	alty under this Act if—
12	(A) the reliance was in good faith;
13	(B) the trustee had no notice of the rev-
14	ocation; and
15	(C) the disclosure was otherwise in accord-
16	ance with the requirements of this section.
17	(e) Additional Requirements of Trustee.—A
18	health information trustee may impose requirements for
19	an authorization that are in addition to the requirements
20	in this section.
21	(f) Copy.—A health information trustee who dis-
22	closes protected health information pursuant to an author-
23	ization under this section shall maintain a copy of the au-
24	thorization.

1	(g) Construction.—This section may not be con-
2	strued—
3	(1) to require a health information trustee to
4	disclose protected health information; or
5	(2) to limit the right of a health information
6	trustee to charge a fee for the disclosure or repro-
7	duction of protected health information.
8	(h) Subpoenas, Warrants, and Search War-
9	RANTS.—If a health information trustee discloses pro-
10	tected health information pursuant to an authorization in
11	order to comply with an administrative subpoena or war-
12	rant or a judicial subpoena or search warrant, the author-
13	ization—
14	(1) shall specifically authorize the disclosure for
15	the purpose of permitting the trustee to comply with
16	the subpoena, warrant, or search warrant; and
17	(2) shall otherwise meet the requirements in
18	this section.
19	CEC 119 THEATMENT DAYMENT AND OVERCIOUT
	SEC. 113. TREATMENT, PAYMENT, AND OVERSIGHT.
20	(a) Disclosures by Plans, Providers, and
2021	
	(a) Disclosures by Plans, Providers, and
2122	(a) DISCLOSURES BY PLANS, PROVIDERS, AND OVERSIGHT AGENCIES.—A health information trustee de-

1	(1) for the purpose of providing health care and
2	a protected individual who is a subject of the infor-
3	mation has not previously objected to the disclosure
4	in writing;
5	(2) for the purpose of providing for the pay-
6	ment for health care furnished to an individual; or
7	(3) for use by a health oversight agency for a
8	purpose that is described in subparagraph (A) or
9	(B) (i) of section $3(b)(7)$.
10	(b) Disclosures by Certain Other Trustees.—
11	A health information trustee may disclose protected health
12	information to a health care provider if—
13	(1) the disclosure is for the purpose described
14	in subsection (a)(1); and
15	(2) the trustee—
16	(A) is a public health authority;
17	(B) received protected health information
18	pursuant to section 117 (relating to emergency
19	circumstances); or
20	(C) is an officer or employee of a trustee
21	described in subsection (B).
22	(c) USE IN ACTION AGAINST INDIVIDUAL.—A person
23	who receives protected health information about a pro-
24	tected individual through a disclosure under this section
25	may not use or disclose the information in any administra-

- 1 tive, civil, or criminal action or investigation directed
- 2 against the individual, except an action or investigation
- 3 arising out of and related to receipt of health care or pay-
- 4 ment for health care.
- 5 (d) APPLICABILITY.—A health information trustee
- 6 referred to in subsection (a) is any of the following:
- 7 (1) A health benefit plan sponsor.
- 8 (2) A health care provider.
- 9 (3) A health oversight agency.
- 10 (4) A health information service organization.
- 11 SEC. 114. NEXT OF KIN AND DIRECTORY INFORMATION.
- 12 (a) NEXT OF KIN.—A health information trustee who
- 13 is a health care provider, who received protected health
- 14 information pursuant to section 117 (relating to emer-
- 15 gency circumstances), or who is an officer or employee of
- 16 such a recipient may orally disclose protected health infor-
- 17 mation about a protected individual to the next of kin of
- 18 the individual (as defined under State law), or to a person
- 19 with whom the individual has a close personal relationship,
- 20 if—
- 21 (1) the trustee has no reason to believe that the
- individual would consider the information especially
- 23 sensitive;
- 24 (2) the individual has not previously objected to
- 25 the disclosure;

1	(3) the disclosure is consistent with good medi-
2	cal or other professional practice; and
3	(4) the information disclosed is limited to infor-
4	mation about health care that is being provided to
5	the individual at or about the time of the disclosure.
6	(b) Directory Information.—
7	(1) IN GENERAL.—A health information trustee
8	who is a health care provider, who received protected
9	health information pursuant to section 117 (relating
10	to emergency circumstances), or who is an officer or
11	employee of a such a recipient may disclose to any
12	person the information described in paragraph (2)
13	if—
14	(A) a protected individual who is a subject
15	of the information has not objected in writing
16	to the disclosure;
17	(B) the disclosure is otherwise consistent
18	with good medical and other professional prac-
19	tice; and
20	(C) the information does not reveal specific
21	information about the physical or mental condi-
22	tion or functional status of a protected individ-
23	ual or about the health care provided to a pro-
24	tected individual.

1	(2) Information described.—The informa-
2	tion referred to in paragraph (1) is the following:
3	(A) The name of an individual receiving
4	health care from a health care provider on a
5	premises controlled by the provider.
6	(B) The location of the individual on such
7	premises.
8	(C) The general health status of the indi-
9	vidual, described in terms of critical, poor, fair,
10	stable, satisfactory, or terms denoting similar
11	conditions.
12	(c) No Accounting Required.—A health informa-
13	tion trustee who discloses protected health information
14	under this section is not required to maintain an account-
15	ing of the disclosure under section 104.
16	(d) Recipients.—A person to whom protected
17	health information is disclosed under this section shall not,
18	by reason of such disclosure, be subject to any require-
19	ment under this Act.
20	SEC. 115. PUBLIC HEALTH.
21	(a) IN GENERAL.—A health information trustee who
22	is a health care provider or a public health authority may
23	disclose protected health information to—
24	(1) a public health authority for use in legally
25	authorized—

1	(A) disease or injury reporting;
2	(B) public health surveillance; or
3	(C) public health investigation or interven-
4	tion; or
5	(2) an individual who is authorized by law to
6	receive the information in a public health interven-
7	tion.
8	(b) USE IN ACTION AGAINST INDIVIDUAL.—A public
9	health authority who receives protected health information
10	about a protected individual through a disclosure under
11	this section may not use or disclose the information in any
12	administrative, civil, or criminal action or investigation di-
13	rected against the individual, except where the use or dis-
14	closure is authorized by law for protection of the public
15	health.
16	(c) Individual Recipients.—An individual to
17	whom protected health information is disclosed under sub-
18	section (a)(2) shall not, by reason of such disclosure, be
19	subject to any requirement under this Act.
20	SEC. 116. HEALTH RESEARCH.
21	(a) IN GENERAL.—A health information trustee de-
22	scribed in subsection (d) may disclose protected health in-
23	formation to a person if—
24	(1) the person is conducting an approved health
25	research project:

1	(2) the information is to be used in the project
2	and
3	(3) the project has been determined by a cer-
4	tified institutional review board to be—
5	(A) of sufficient importance so as to out-
6	weigh the intrusion into the privacy of the pro-
7	tected individual who is the subject of the infor-
8	mation that would result from the disclosure
9	and
10	(B) impracticable to conduct without the
11	information.
12	(b) Disclosures by Health Information Serv-
13	ICE ORGANIZATIONS.—A health information service orga-
14	nization may disclose protected health information under
15	subsection (a) only if the certified institutional review
16	board referred to in subsection (a)(3) has been certified
17	as being qualified to make determinations under such sub-
18	section with respect to disclosures by such organizations.
19	(c) Limitations on Use and Disclosure; Obliga-
20	TIONS OF RECIPIENT.—A health researcher who receives
21	protected health information about a protected individual
22	pursuant to subsection (a)—
23	(1) may use the information solely for purposes
24	of an approved health research project;

1	(2) may not use or disclose the information in
2	any administrative, civil, or criminal action or inves-
3	tigation directed against the individual; and
4	(3) shall remove or destroy, at the earliest op-
5	portunity consistent with the purposes of the ap-
6	proved health research project in connection with
7	which the disclosure was made, information that
8	would enable an individual to be identified, unless a
9	certified institutional review board has determined
10	that there is a health or research justification for re-
11	tention of such identifiers and there is an adequate
12	plan to protect the identifiers from use and disclo-
13	sure that is inconsistent with this Act.
14	(d) Applicability.—A health information trustee
15	referred to in subsection (a) is any health information
16	trustee other than a person who, with respect to the spe-
17	cific protected health information to be disclosed under
18	such subsection, received the information—
19	(1) pursuant to—
20	(A) section 118 (relating to judicial and
21	administrative purposes);
22	(B) paragraph (1), (2), (3), or (4) of sec-
23	tion 119(a) (relating to law enforcement); or
24	(C) section 120 (relating to subpoenas,
25	warrants, and search warrants); or

- 1 (2) while acting in whole or in part in the ca-2 pacity of an officer or employee of a person de-3 scribed in paragraph (1).
- 4 (e) Requirements for Institutional Review 5 Boards.—
 - (1) REGULATIONS.—Not later than July 1, 1996, the Secretary, after opportunity for notice and comment, shall promulgate regulations establishing requirements for certified institutional review boards under this Act. The regulations shall be based on regulations promulgated under section 491(a) of the Public Health Service Act and shall ensure that certified institutional review boards are qualified to assess and protect the confidentiality of research subjects. The regulations shall include specific requirements for certified institutional review boards that make determinations under subsection (a)(3) with respect to disclosures by health information service organizations.
 - (2) CERTIFICATION.—The Secretary shall certify that an institutional review board satisfies the requirements of the regulations promulgated under paragraph (1).

1 SEC. 117. EMERGENCY CIRCUMSTANCES.

- 2 (a) IN GENERAL.—A health information trustee may
- 3 disclose protected health information if the trustee be-
- 4 lieves, on reasonable grounds, that the disclosure is nec-
- 5 essary to prevent or lessen a serious and imminent threat
- 6 to the health or safety of an individual.
- 7 (b) Use in Action Against Individual.—A person
- 8 who receives protected health information about a pro-
- 9 tected individual through a disclosure under this section
- 10 may not use or disclose the information in any administra-
- 11 tive, civil, or criminal action or investigation directed
- 12 against the individual, except an action or investigation
- 13 arising out of and related to receipt of health care or pay-
- 14 ment for health care.

15 SEC. 118. JUDICIAL AND ADMINISTRATIVE PURPOSES.

- 16 (a) IN GENERAL.—A health information trustee de-
- 17 scribed in subsection (d) may disclose protected health in-
- 18 formation—
- (1) pursuant to the Federal Rules of Civil Pro-
- cedure, the Federal Rules of Criminal Procedure, or
- comparable rules of other courts or administrative
- agencies in connection with litigation or proceedings
- 23 to which a protected individual who is a subject of
- 24 the information is a party and in which the individ-
- ual has placed the individual's physical or mental
- condition or functional status in issue;

1	(2) if directed by a court in connection with a
2	court-ordered examination of an individual; or
3	(3) to assist in the identification of a dead
4	individual.
5	(b) Written Statement.—A person seeking pro-
6	tected health information about a protected individual held
7	by health information trustee under—
8	(1) subsection (a)(1)—
9	(A) shall notify the protected individual or
10	the attorney of the protected individual of the
11	request for the information;
12	(B) shall provide the trustee with a signed
13	document attesting—
14	(i) that the protected individual is a
15	party to the litigation or proceedings for
16	which the information is sought;
17	(ii) that the individual has placed the
18	individual's physical or mental condition or
19	functional status in issue; and
20	(iii) the date on which the protected
21	individual or the attorney of the protected
22	individual was notified under subparagraph
23	(A); and
24	(C) shall not accept any requested pro-
25	tected health information from the trustee until

1	the termination of the 10-day period beginning
2	on the date notice was given under subpara-
3	graph (A); or
4	(2) subsection (a)(3) shall provide the trustee
5	with a written statement that the information is
6	sought to assist in the identification of a dead
7	individual.
8	(c) Use and Disclosure.—A person to whom pro-
9	tected health information is disclosed under this section
10	may use and disclose the information only to accomplish
11	the purpose for which the disclosure was made.
12	(d) Applicability.—A health information trustee
13	referred to in subsection (a) is any of the following:
14	(1) A health benefit plan sponsor.
15	(2) A health care provider.
16	(3) A health oversight agency.
17	(4) A person who, with respect to the specific
18	protected health information to be disclosed under
19	such subsection, received the information—
20	(A) pursuant to—
21	(i) section 117 (relating to emergency
22	circumstances); or
23	(ii) section 120 (relating to subpoe-
24	nas, warrants, and search warrants); or

1	(B) while acting in whole or in part in the
2	capacity of an officer or employee of a person
3	described in subparagraph (A).
4	SEC. 119. LAW ENFORCEMENT.
5	(a) In General.—A health information trustee,
6	other than a health information service organization, may
7	disclose protected health information to a law enforcement
8	agency, other than a health oversight agency—
9	(1) if the information is disclosed for use in an
10	investigation or prosecution of a health information
11	trustee;
12	(2) in connection with criminal activity commit-
13	ted against the trustee or an affiliated person of the
14	trustee or on premises controlled by the trustee; or
15	(3) if the information is needed to determine
16	whether a crime has been committed and the nature
17	of any crime that may have been committed (other
18	than a crime that may have been committed by the
19	protected individual who is the subject of the infor-
20	mation).
21	(b) Additional Authority of Certain Trust-
22	EES.—A health information trustee who is not a health
23	information service organization, a public health author-

24 ity, or a health researcher may disclose protected health

1	information to a law enforcement agency (other than a
2	health oversight agency)—
3	(1) to assist in the identification or location of
4	a victim, fugitive, or witness in a law enforcement
5	inquiry;
6	(2) pursuant to a law requiring the reporting of
7	specific health care information to law enforcement
8	authorities; or
9	(3) if the information is specific health informa-
10	tion described in paragraph (2) and the trustee is
11	operated by a Federal agency;
12	(c) CERTIFICATION.—Where a law enforcement agen-
13	cy requests a health information trustee to disclose pro-
14	tected health information under subsection (a) or (b)(1),
15	the agency shall provide the trustee with a written certifi-
16	cation that—
17	(1) is signed by a supervisory official of a rank
18	designated by the head of the agency;
19	(2) specifies the information requested; and
20	(3) states that the information is needed for a
21	lawful purpose under this section.
22	(d) Restrictions on Disclosure and Use.—A
23	person who receives protected health information about a
24	protected individual through a disclosure under this sec-
25	tion may not use or disclose the information—

- 1 (1) in any administrative, civil, or criminal ac-2 tion or investigation directed against the individual, 3 except an action or investigation arising out of and 4 directly related to the action or investigation for 5 which the information was obtained; and
- 6 (2) otherwise unless the use or disclosure is 7 necessary to fulfill the purpose for which the infor-8 mation was obtained and is not prohibited by any 9 other provision of law.
- 10 SEC. 120. SUBPOENAS, WARRANTS, AND SEARCH WAR-11 RANTS.
- 12 (a) IN GENERAL.—A health information trustee de-13 scribed in subsection (g) may disclose protected health in-14 formation if the disclosure is pursuant to any of the fol-15 lowing:
 - (1) A subpoena issued under the authority of a grand jury and the trustee is provided a written certification by the grand jury that the grand jury has complied with the applicable access provisions of section 5151.
 - (2) An administrative subpoena or warrant or a judicial subpoena or search warrant and the trustee is provided a written certification by the person seeking the information that the person has com-

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- plied with the applicable access provisions of section 131 or 133(a).
- 3 (3) An administrative subpoena or warrant or 4 a judicial subpoena or search warrant and the dis-5 closure otherwise meets the conditions of one of sec-6 tions 113 through 119.
- 7 (b) AUTHORITY OF ALL TRUSTEES.—Any health in-8 formation trustee may disclose protected health informa-9 tion if the disclosure is pursuant to subsection (a)(3).
- 10 (c) RESTRICTIONS ON USE AND DISCLOSURE.—Pro-11 tected health information about a protected individual that 12 is disclosed by a health information trustee pursuant to—
 - (1) subsection (a)(2) may not be otherwise used or disclosed by the recipient unless the use or disclosure is necessary to fulfill the purpose for which the information was obtained; and
 - (2) subsection (a)(3) may not be used or disclosed by the recipient unless the recipient complies with the conditions and restrictions on use and disclosure with which the recipient would have been required to comply if the disclosure by the trustee had been made under the section referred to in subsection (a)(3) the conditions of which were met by the disclosure.

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- 1 (d) RESTRICTIONS ON GRAND JURIES.—Protected 2 health information that is disclosed by a health informa-3 tion trustee under subsection (a)(1)—
- 4 (1) shall be returnable on a date when the 5 grand jury is in session and actually presented to 6 the grand jury;
 - (2) shall be used only for the purpose of considering whether to issue an indictment or report by that grand jury, or for the purpose of prosecuting a crime for which that indictment or report is issued, or for a purpose authorized by rule 6(e) of the Federal Rules of Criminal Procedure or a comparable State rule;
 - (3) shall be destroyed or returned to the trustee if not used for one of the purposes specified in paragraph (2); and
 - (4) shall not be maintained, or a description of the contents of such information shall not be maintained, by any government authority other than in the sealed records of the grand jury, unless such information has been used in the prosecution of a crime for which the grand jury issued an indictment or presentment or for a purpose authorized by rule 6(e) of the Federal Rules of Criminal Procedure or a comparable State rule.

- 1 (e) Use in Action Against Individual.—A person
- 2 who receives protected health information about a pro-
- 3 tected individual through a disclosure under this section
- 4 may not use or disclose the information in any administra-
- 5 tive, civil, or criminal action or investigation directed
- 6 against the individual, except an action or investigation
- 7 arising out of and directly related to the inquiry for which
- 8 the information was obtained;
- 9 (f) Construction.—Nothing in this section shall be
- 10 construed as authority for a health information trustee to
- 11 refuse to comply with a valid administrative subpoena or
- 12 warrant or a valid judicial subpoena or search warrant
- 13 that meets the requirements of this Act.
- 14 (g) APPLICABILITY.—A health information trustee
- 15 referred to in subsection (a) is any trustee other than the
- 16 following:
- 17 (1) A health information service organization.
- 18 (2) A public health authority.
- 19 (3) A health researcher.
- 20 SEC. 121. HEALTH INFORMATION SERVICE ORGANIZA-
- 21 TIONS.
- A health information trustee may disclose protected
- 23 health information to a health information service organi-
- 24 zation for the purpose of permitting the organization to
- 25 perform a function for which the Secretary has authorized

- 1 (by means of a designation or certification) the organiza-
- 2 tion to receive access to specific health care data in elec-
- 3 tronic or magnetic form.

Subtitle C—Access Procedures and Challenge Rights

- 6 SEC. 131. ACCESS PROCEDURES FOR LAW ENFORCEMENT
- 7 SUBPOENAS, WARRANTS, AND SEARCH WAR-
- 8 RANTS.
- 9 (a) Probable Cause Requirement.—A govern-
- 10 ment authority may not obtain protected health informa-
- 11 tion about a protected individual from a health informa-
- 12 tion trustee under paragraph (1) or (2) of section 120(a)
- 13 for use in a law enforcement inquiry unless there is prob-
- 14 able cause to believe that the information is relevant to
- 15 a legitimate law enforcement inquiry being conducted by
- 16 the government authority.
- 17 (b) Warrants and Search Warrants.—A govern-
- 18 ment authority that obtains protected health information
- 19 about a protected individual from a health information
- 20 trustee under circumstances described in subsection (a)
- 21 and pursuant to a warrant or search warrant shall, not
- 22 later than 30 days after the date the warrant was served
- 23 on the trustee, serve the individual with, or mail to the
- 24 last known address of the individual, a copy of the war-
- 25 rant.

- (c) Subpoenas.—Except as provided in subsection 1 (d), a government authority may not obtain protected 2 health information about a protected individual from a health information trustee under circumstances described in subsection (a) and pursuant to a subpoena unless a copy of the subpoena has been served by hand delivery upon the individual, or mailed to the last known address 8 of the individual, on or before the date on which the subpoena was served on the trustee, together with a notice (published by the Secretary under section 135(1)) of the 10 individual's right to challenge the subpoena in accordance with section 132, and— 12
- 13 (1) 30 days have passed from the date of serv-14 ice, or 30 days have passed from the date of mailing, 15 and within such time period the individual has not 16 initiated a challenge in accordance with section 132; 17 or
 - (2) disclosure is ordered by a court under section 132.

(d) Application for Delay.—

(1) IN GENERAL.—A government authority may apply to an appropriate court to delay (for an initial period of not longer than 90 days) serving a copy of a subpoena and a notice otherwise required under subsection (c) with respect to a law enforcement in-

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- quiry. The government authority may apply to the 1 2 court for extensions of the delay. (2) Reasons for Delay.—An application for 3 a delay, or extension of a delay, under this subsection shall state, with reasonable specificity, the 5 reasons why the delay or extension is being sought. 6 7 (3) Ex parte order.—The court shall enter an ex parte order delaying, or extending the delay 8 of, the notice and an order prohibiting the trustee 9 from revealing the request for, or the disclosure of, 10 the protected health information being sought if the 11 12 court finds that— (A) the inquiry being conducted is within 13 the lawful jurisdiction of the government au-14 15 thority seeking the protected health informa-16 tion; 17 (B) there is probable cause to believe that 18 the protected health information being sought is 19 relevant to a legitimate law enforcement inquiry 20 being conducted by the government authority; (C) the government authority's need for 21
- the information outweighs the privacy interest of the protected individual who is the subject of the information; and

1	(D) there are reasonable grounds to believe
2	that receipt of a notice by the individual will re-
3	sult in—
4	(i) endangering the life or physical
5	safety of any individual;
6	(ii) flight from prosecution;
7	(iii) destruction of or tampering with
8	evidence or the information being sought;
9	or
10	(iv) intimidation of potential wit-
11	nesses.
12	(4) Service of application on individ-
13	UAL.—Upon the expiration of a period of delay of
14	notice under this subsection, the government author-
15	ity shall serve upon the individual, with the service
16	of the subpoena and the notice, a copy of any appli-
17	cations filed and approved under this subsection.
18	SEC. 132. CHALLENGE PROCEDURES FOR LAW ENFORCE-
19	MENT SUBPOENAS.
20	(a) MOTION TO QUASH SUBPOENA.—Within 30 days
21	of the date of service, or 30 days of the date of mailing,
	of a subpoena of a government authority seeking protected
	health information about a protected individual from a
	health information trustee under paragraph (1) or (2) of
25	section 120(a) (except a subpoena to which section 133

1	applies), the individual may file (without filing fee) a mo-
2	tion to quash the subpoena—
3	(1) in the case of a State judicial subpoena, in
4	the court which issued the subpoena;
5	(2) in the case of a subpoena issued under the
6	authority of a State that is not a State judicial sub-
7	poena, in a court of competent jurisdiction;
8	(3) in the case of a subpoena issued under the
9	authority of a Federal court, in any court of the
10	United States of competent jurisdiction; or
11	(4) in the case of any other subpoena issued
12	under the authority of the United States, in-
13	(A) the United States district court for the
14	district in which the individual resides or in
15	which the subpoena was issued; or
16	(B) another United States district court of
17	competent jurisdiction.
18	(b) Copy.—A copy of the motion shall be served by
19	the individual upon the government authority by delivery
20	of registered or certified mail.
21	(c) Affidavits and Sworn Documents.—The gov-
22	ernment authority may file with the court such affidavits
23	and other sworn documents as sustain the validity of the
24	subpoena. The individual may file with the court, within
25	5 days of the date of the authority's filing, affidavits and

- 1 sworn documents in response to the authority's filing. The
- 2 court, upon the request of the individual, the government
- 3 authority, or both, may proceed in camera.
- 4 (d) Proceedings and Decision on Motion.—The
- 5 court may conduct such proceedings as it deems appro-
- 6 priate to rule on the motion. All such proceedings shall
- 7 be completed, and the motion ruled on, within 10 calendar
- 8 days of the date of the government authority's filing.
- 9 (e) Extension of Time Limits for Good
- 10 CAUSE.—The court, for good cause shown, may at any
- 11 time in its discretion enlarge the time limits established
- 12 by subsections (c) and (d).
- 13 (f) STANDARD FOR DECISION.—A court may deny a
- 14 motion under subsection (a) if it finds that there is prob-
- 15 able cause to believe that the protected health information
- 16 being sought is relevant to a legitimate law enforcement
- 17 inquiry being conducted by the government authority, un-
- 18 less the court finds that the individual's privacy interest
- 19 outweighs the government authority's need for the infor-
- 20 mation. The individual shall have the burden of dem-
- 21 onstrating that the individual's privacy interest outweighs
- 22 the need established by the government authority for the
- 23 information.
- 24 (g) Specific Considerations With Respect to
- 25 Privacy Interest.—In determining under subsection (f)

- 1 whether an individual's privacy interest outweighs the gov-
- 2 ernment authority's need for the information, the court
- 3 shall consider—
- 4 (1) the particular purpose for which the information was collected by the trustee;
- 6 (2) the degree to which disclosure of the information will embarrass, injure, or invade the privacy of the individual;
- 9 (3) the effect of the disclosure on the individ-10 ual's future health care:
- 11 (4) the importance of the inquiry being con-12 ducted by the government authority, and the impor-13 tance of the information to that inquiry; and
- 14 (5) any other factor deemed relevant by the court.
- 16 (h) ATTORNEY'S FEES.—In the case of any motion
- 17 brought under subsection (a) in which the individual has
- 18 substantially prevailed, the court, in its discretion, may as-
- 19 sess against a government authority a reasonable attor-
- 20 ney's fee and other litigation costs (including expert fees)
- 21 reasonably incurred.
- 22 (i) No Interlocutory Appeal.—A court ruling de-
- 23 nying a motion to quash under this section shall not be
- 24 deemed a final order and no interlocutory appeal may be
- 25 taken therefrom by the individual. An appeal of such a

1	ruling may be taken by the individual within such period
2	of time as is provided by law as part of any appeal from
3	a final order in any legal proceeding initiated against the
4	individual arising out of or based upon the protected
5	health information disclosed.
6	SEC. 133. ACCESS AND CHALLENGE PROCEDURES FOR
7	OTHER SUBPOENAS.
8	(a) IN GENERAL.—A person (other than a govern-
9	ment authority seeking protected health information under
10	circumstances described in section 131(a)) may not obtain
11	protected health information about a protected individual
12	from a health information trustee pursuant to a subpoena
13	under section 120(a)(2) unless—
14	(1) a copy of the subpoena has been served
15	upon the individual or mailed to the last known ad-
16	dress of the individual on or before the date on
17	which the subpoena was served on the trustee, to-
18	gether with a notice (published by the Secretary
19	under section 135(2)) of the individual's right to
20	challenge the subpoena, in accordance with sub-
21	section (b); and
22	(2) either—
23	(A) 30 days have passed from the date of
24	service or 30 days have passed from the date of
25	the mailing and within such time period the in-

1	dividual has not initiated a challenge in accord-
2	ance with subsection (b); or
3	(B) disclosure is ordered by a court under
4	such subsection.
5	(b) MOTION TO QUASH.—Within 30 days of the date
6	of service or 30 days of the date of mailing of a subpoena
7	seeking protected health information about a protected in-
8	dividual from a health information trustee under sub-
9	section (a), the individual may file (without filing fee) in
10	any court of competent jurisdiction, a motion to quash the
11	subpoena, with a copy served on the person seeking the
12	information. The individual may oppose, or seek to limit,
13	the subpoena on any grounds that would otherwise be
14	available if the individual were in possession of the infor-
15	mation.
16	(c) Standard for Decision.—The court shall
17	grant an individual's motion under subsection (b) if the
18	person seeking the information has not sustained the bur-
19	den of demonstrating that—
20	(1) there are reasonable grounds to believe that
21	the information will be relevant to a lawsuit or other
22	judicial or administrative proceeding; and
23	(2) the need of the person for the information
24	outweighs the privacy interest of the individual.

1	(d) Specific Considerations With Respect to
2	PRIVACY INTEREST.—In determining under subsection (c)
3	whether the need of the person for the information out-
4	weighs the privacy interest of the individual, the court
5	shall consider—
6	(1) the particular purpose for which the infor-
7	mation was collected by the trustee;
8	(2) the degree to which disclosure of the infor-
9	mation will embarrass, injure, or invade the privacy
10	of the individual;
11	(3) the effect of the disclosure on the individ-
12	ual's future health care;
13	(4) the importance of the information to the
14	lawsuit or proceeding; and
15	(5) any other factor deemed relevant by the
16	court.
17	(e) ATTORNEY'S FEES.—In the case of any motion
18	brought under subsection (b) by an individual against a
19	person in which the individual has substantially prevailed,
20	the court, in its discretion, may assess against the person
21	a reasonable attorney's fee and other litigation costs (in-
22	cluding expert fees) reasonably incurred.

1	SEC. 134. CONSTRUCTION OF SUBTITLE; SUSPENSION OF
2	STATUTE OF LIMITATIONS.
3	(a) IN GENERAL.—Nothing in this subtitle shall af-
4	fect the right of a health information trustee to challenge
5	a request for protected health information. Nothing in this
6	subtitle shall entitle a protected individual to assert the
7	rights of a health information trustee.
8	(b) Effect of Motion on Statute of Limita-
9	TIONS.—If an individual who is the subject of protected
10	health information files a motion under this subtitle which
11	has the effect of delaying the access of a government au-
12	thority to such information, the period beginning on the
13	date such motion was filed and ending on the date on
14	which the motion is decided shall be excluded in computing
15	any period of limitations within which the government au-
16	thority may commence any civil or criminal action in con-
17	nection with which the access is sought.
18	SEC. 135. RESPONSIBILITIES OF SECRETARY.
19	Not later than July 1, 1996, the Secretary, after no-
20	tice and opportunity for public comment, shall develop and
21	disseminate brief, clear, and easily understood model
22	notices—
23	(1) for use under subsection (c) of section 131,
24	detailing the rights of a protected individual who
25	wishes to challenge, under section 132, the disclo-

- sure of protected health information about the individual under such subsection; and (2) for use under subsection (a) of section 133,
 - (2) for use under subsection (a) of section 133, detailing the rights of a protected individual who wishes to challenge, under subsection (b) of such section, the disclosure of protected health information about the individual under such section.

Subtitle D—Miscellaneous Provisions

10 SEC. 141. PAYMENT CARD AND ELECTRONIC PAYMENT

11 TRANSACTIONS.

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- 12 (a) Payment for Health Care Through Card
- 13 OR ELECTRONIC MEANS.—If a protected individual pays
- 14 a health information trustee for health care by presenting
- 15 a debit, credit, or other payment card or account number,
- 16 or by any other electronic payment means, the trustee may
- 17 disclose to a person described in subsection (b) only such
- 18 protected health information about the individual as is
- 19 necessary for the processing of the payment transaction
- 20 or the billing or collection of amounts charged to, debited
- 21 from, or otherwise paid by, the individual using the card,
- 22 number, or other electronic payment means.
- 23 (b) Transaction Processing.—A person who is a
- 24 debit, credit, or other payment card issuer, is otherwise
- 25 directly involved in the processing of payment transactions

- 1 involving such cards or other electronic payment trans-
- 2 actions, or is otherwise directly involved in the billing or
- 3 collection of amounts paid through such means, may only
- 4 use or disclose protected health information about a pro-
- 5 tected individual that has been disclosed in accordance
- 6 with subsection (a) when necessary for—
- 7 (1) the authorization, settlement, billing or col-
- 8 lection of amounts charged to, debited from, or oth-
- 9 erwise paid by, the individual using a debit, credit,
- or other payment card or account number, or by
- other electronic payment means;
- 12 (2) the transfer of receivables, accounts, or in-
- terest therein;
- 14 (3) the audit of the credit, debit, or other pay-
- ment card account information;
- 16 (4) compliance with Federal, State, or local law;
- 17 or
- 18 (5) a properly authorized civil, criminal, or reg-
- 19 ulatory investigation by Federal, State, or local au-
- thorities.
- 21 SEC. 142. ACCESS TO PROTECTED HEALTH INFORMATION
- 22 **OUTSIDE OF THE UNITED STATES.**
- 23 (a) In General.—Notwithstanding the provisions of
- 24 subtitle B, and except as provided in subsection (b), a
- 25 health information trustee may not permit any person who

- 1 is not in a State to have access to protected health infor-
- 2 mation about a protected individual unless one or more
- 3 of the following conditions exist:
- 4 (1) Specific authorization.—The individual has specifically consented to the provision of such access outside of the United States in an authorization that meets the requirements of section 112.
- (2) Equivalent protection.—The provision 8 of such access is authorized under this Act and the 9 Secretary has determined that there are fair infor-10 11 mation practices for protected health information in the jurisdiction where the access will be provided 12 that provide protections for individuals and pro-13 14 tected health information that are equivalent to the 15 protections provided for by this Act.
 - (3) Access required by Law.—The provision of such access is required under—
- 18 (A) a Federal statute; or
- 19 (B) a treaty or other international agree-20 ment applicable to the United States.
- 21 (b) Exceptions.—Subsection (a) does not apply
- 22 where the provision of access to protected health informa-
- 23 tion—

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24 (1) is to a foreign public health authority;

- 1 (2) is authorized under section 114 (relating to 2 next of kin and directory information), 116 (relating 3 to health research), or 117 (relating to emergency 4 circumstances); or
- 5 (3) is necessary for the purpose of providing for 6 payment for health care that has been provided to 7 an individual.

8 SEC. 143. STANDARDS FOR ELECTRONIC DOCUMENTS AND

9 **COMMUNICATIONS.**

- 10 (a) STANDARDS.—Not later than July 1, 1996, the 11 Secretary, after notice and opportunity for public com-
- 12 ment and in consultation with appropriate private stand-
- 13 ard-setting organizations and other interested parties,
- 14 shall establish standards with respect to the creation,
- 15 transmission, receipt, and maintenance, in electronic and
- 16 magnetic form, of each type of written document specifi-
- 17 cally required or authorized under this Act. Where a sig-
- 18 nature is required under any other provision of this Act,
- 19 such standards shall provide for an electronic or magnetic
- 20 substitute that serves the functional equivalent of a signa-
- 21 ture.
- 22 (b) Treatment of Complying Documents and
- 23 COMMUNICATIONS.—An electronic or magnetic document
- 24 or communication that satisfies the standards established
- 25 under subsection (a) with respect to such document or

1	communication shall be treated as satisfying the require-
2	ments of this Act that apply to an equivalent written docu-
3	ment.
4	SEC. 144. DUTIES AND AUTHORITIES OF AFFILIATED PER
5	SONS.
6	(a) Requirements on Trustees.—
7	(1) Provision of information.—A health in-
8	formation trustee may provide protected health in-
9	formation to a person who, with respect to the trust-
10	ee, is an affiliated person and may permit the affili-
11	ated person to use such information, only for the
12	purpose of conducting, supporting, or facilitating ar
13	activity that the trustee is authorized to undertake
14	(2) Notice to affiliated person.—A health
15	information trustee shall notify a person who, with
16	respect to the trustee, is an affiliated person of any
17	duties under this Act that the affiliated person is re-
18	quired to fulfill and of any authorities under this
19	Act that the affiliated person is authorized to exer-
20	cise.
21	(b) Duties of Affiliated Persons.—
22	(1) IN GENERAL.—An affiliated person shall
23	fulfill any duty under this Act that—
24	(A) the health information trustee with
25	whom the person has an agreement or relation-

- ship described in section 3(c)(1)(C) is required to fulfill; and
 - (B) the person has undertaken to fulfill pursuant to such agreement or relationship.
 - (2) Construction of other subtitles.— With respect to a duty described in paragraph (1) that an affiliated person is required to fulfill, the person shall be considered a health information trustee for purposes of this Act. The person shall be subject to subtitle E (relating to enforcement) with respect to any such duty that the person fails to fulfill.
 - (3) EFFECT ON TRUSTEE.—An agreement or relationship with an affiliated person does not relieve a health information trustee of any duty or liability under this Act.

(b) Authorities of Affiliated Persons.—

(1) IN GENERAL.—An affiliated person may only exercise an authority under this Act that the health information trustee with whom the person is affiliated may exercise and that the person has been given by the trustee pursuant to an agreement or relationship described in section 3(c)(1)(C). With respect to any such authority, the person shall be considered a health information trustee for purposes of

- this Act. The person shall be subject to subtitle E
- 2 (relating to enforcement) with respect to any act
- 3 that exceeds such authority.
- 4 (2) Effect on trustee.—An agreement or
- 5 relationship with an affiliated person does not affect
- 6 the authority of a health information trustee under
- 7 this Act.

8 SEC. 145. AGENTS AND ATTORNEYS.

- 9 (a) IN GENERAL.—Except as provided in subsections
- 10 (b) and (c), a person who is authorized by law (on grounds
- 11 other than an individual's minority), or by an instrument
- 12 recognized under law, to act as an agent, attorney, proxy,
- 13 or other legal representative for a protected individual or
- 14 the estate of a protected individual, or otherwise to exer-
- 15 cise the rights of the individual or estate, may, to the ex-
- 16 tent authorized, exercise and discharge the rights of the
- 17 individual or estate under this Act.
- 18 (b) Health Care Power of Attorney.—A person
- 19 who is authorized by law (on grounds other than an indi-
- 20 vidual's minority), or by an instrument recognized under
- 21 law, to make decisions about the provision of health care
- 22 to an individual who is incapacitated may exercise and dis-
- 23 charge the rights of the individual under this Act to the
- 24 extent necessary to effectuate the terms or purposes of
- 25 the grant of authority.

1	(c) No Court Declaration.—If a health care pro-
2	vider determines that an individual, who has not been de-
3	clared to be legally incompetent, suffers from a medical
4	condition that prevents the individual from acting know-
5	ingly or effectively on the individual's own behalf, the right
6	of the individual to authorize disclosure under section 112
7	may be exercised and discharged in the best interest of
8	the individual by—
9	(1) a person described in subsection (b) with re-
10	spect to the individual;
11	(2) a person described in subsection (a) with re-
12	spect to the individual, but only if a person de-
13	scribed in paragraph (1) cannot be contacted after
14	a reasonable effort;
15	(3) the next of kin of the individual, but only
16	if a person described in paragraph (1) or (2) cannot
17	be contacted after a reasonable effort; or
18	(4) the health care provider, but only if a per-
19	son described in paragraph (1), (2), or (3) cannot be
20	contacted after a reasonable effort.
21	SEC. 146. MINORS.
22	(a) Individuals Who Are 18 or Legally Capa-

23 BLE.—In the case of an individual—

- 1 (1) who is 18 years of age or older, all rights 2 of the individual shall be exercised by the individual, 3 except as provided in section 145; or
 - (2) who, acting alone, has the legal capacity to apply for and obtain health care and has sought such care, the individual shall exercise all rights of an individual under this Act with respect to protected health information relating to such care.
- 9 (b) Individuals Under 18.—Except as provided in 10 subsection (a)(2), in the case of an individual who is—
- 11 (1) under 14 years of age, all the individual's 12 rights under this Act shall be exercised through the 13 parent or legal guardian of the individual; or
 - (2) 14, 15, 16, or 17 years of age, the right of inspection (under section 101), the right of amendment (under section 102), and the right to authorize disclosure of protected health information (under section 112) of the individual may be exercised either by the individual or by the parent or legal guardian of the individual.

21 SEC. 147. MAINTENANCE OF CERTAIN PROTECTED HEALTH

22 **INFORMATION.**

23 (a) IN GENERAL.—A State shall establish a process 24 under which the protected health information described in 25 subsection (b) that is maintained by a person described

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1	in subsection (c) is delivered to, and maintained by, the
2	State or an individual or entity designated by the State.
3	(b) Information Described.—The protected
4	health information referred to in subsection (a) is pro-
5	tected health information that—
6	(1) is recorded in any form or medium;
7	(2) is created by—
8	(A) a health care provider; or
9	(B) a health benefit plan sponsor that pro-
10	vides benefits in the form of items and services
11	to enrollees and not in the form of reimburse-
12	ment for items and services; and
13	(3) relates in any way to the past, present, or
14	future physical or mental health or condition or
15	functional status of a protected individual or the
16	provision of health care to a protected individual.
17	(c) Persons Described.—A person referred to in
18	subsection (a) is any of the following:
19	(1) A health care facility previously located in
20	the State that has closed.
21	(2) A professional practice previously operated
22	by a health care provider in the State that has
23	closed.
24	(3) A health benefit plan sponsor that—

· -
(A) previously provided benefits in the
form of items and services to enrollees in the
State; and
(B) has ceased to do business.
Subtitle E—Enforcement
SEC. 151. CIVIL ACTIONS.
(a) In General.—Any individual whose right under
this Act has been knowingly or negligently violated—
(1) by a health information trustee, or any
other person, who is not described in paragraph (2),
(3), (4), or (5) may maintain a civil action for actual
damages and for equitable relief against the health
information trustee or other person;
(2) by an officer or employee of the United
States while the officer or employee was acting with-
in the scope of the office or employment may main-
tain a civil action for actual damages and for equi-
table relief against the United States;
(3) by an officer or employee of any government
authority of a State that has waived its sovereign
immunity to a claim for damages resulting from a
violation of this Act while the officer or employee
was acting within the scope of the office or employ-

ment may maintain a civil action for actual damages

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- and for equitable relief against the State government;
- (4) by an officer or employee of a government of a State that is not described in paragraph (3) may maintain a civil action for actual damages and for equitable relief against the officer or employee; or
- 8 (5) by an officer or employee of a government 9 authority while the officer or employee was not act-10 ing within the scope of the office or employment 11 may maintain a civil action for actual damages and 12 for equitable relief against the officer or employee.
- 13 (b) Knowing Violations.—Any individual entitled 14 to recover actual damages under this section because of 15 a knowing violation of a provision of this Act (other than 16 subsection (c) or (d) of section 111) shall be entitled to 17 recover the amount of the actual damages demonstrated 18 or \$5000, whichever is greater.
- 19 (c) ACTUAL DAMAGES.—For purposes of this section, 20 the term "actual damages" includes damages paid to com-21 pensate an individual for nonpecuniary losses such as 22 physical and mental injury as well as damages paid to 23 compensate for pecuniary losses.
- 24 (d) Punitive Damages; Attorney's Fees.—In 25 any action brought under this section in which the com-

- 1 plainant has prevailed because of a knowing violation of
- 2 a provision of this Act (other than subsection (c) or (d)
- 3 of section 111), the court may, in addition to any relief
- 4 awarded under subsections (a) and (b), award such puni-
- 5 tive damages as may be warranted. In such an action, the
- 6 court, in its discretion, may allow the prevailing party a
- 7 reasonable attorney's fee (including expert fees) as part
- 8 of the costs, and the United States shall be liable for costs
- 9 the same as a private person.
- 10 (e) Limitation.—A civil action under this section
- 11 may not be commenced more than 2 years after the date
- 12 on which the aggrieved individual discovered the violation
- 13 or the date on which the aggrieved individual had a rea-
- 14 sonable opportunity to discover the violation, whichever oc-
- 15 curs first.
- 16 (f) INSPECTION AND AMENDMENT.—If a health in-
- 17 formation trustee has established a formal internal proce-
- 18 dure that allows an individual who has been denied inspec-
- 19 tion or amendment of protected health information to ap-
- 20 peal the denial, the individual may not maintain a civil
- 21 action in connection with the denial until the earlier of—
- (1) the date the appeal procedure has been ex-
- 23 hausted; or
- 24 (2) the date that is 4 months after the date on
- which the appeal procedure was initiated.

- 1 (g) No Liability for Permissible Disclo-
- 2 SURES.—A health information trustee who makes a disclo-
- 3 sure of protected health information about a protected in-
- 4 dividual that is permitted by this Act and not otherwise
- 5 prohibited by State or Federal statute shall not be liable
- 6 to the individual for the disclosure under common law.
- 7 (h) No Liability for Institutional Review
- 8 BOARD DETERMINATIONS.—If the members of a certified
- 9 institutional review board have in good faith determined
- 10 that an approved health research project is of sufficient
- 11 importance so as to outweigh the intrusion into the privacy
- 12 of an individual pursuant to section 116(a)(1), the mem-
- 13 bers, the board, and the parent institution of the board
- 14 shall not be liable to the individual as a result of such
- 15 determination.
- 16 (i) GOOD FAITH RELIANCE ON CERTIFICATION.—A
- 17 health information trustee who relies in good faith on a
- 18 certification by a government authority or other person
- 19 and discloses protected health information about an indi-
- 20 vidual in accordance with this Act shall not be liable to
- 21 the individual for such disclosure.
- 22 SEC. 152. CIVIL MONEY PENALTIES.
- 23 (a) VIOLATION.—Any health information trustee who
- 24 the Secretary determines has demonstrated a pattern or
- 25 practice of failure to comply with the provisions of this

- 1 Act shall be subject, in addition to any other penalties that
- 2 may be prescribed by law, to a civil money penalty of not
- 3 more than \$10,000 for each such failure. In determining
- 4 the amount of any penalty to be assessed under the proce-
- 5 dures established under subsection (b), the Secretary shall
- 6 take into account the previous record of compliance of the
- 7 person being assessed with the applicable requirements of
- 8 this Act and the gravity of the violation.
- 9 (b) Procedures for Imposition of Penalties.—
- 10 The provisions of section 1128A of the Social Security Act
- 11 (other than subsections (a) and (b)) shall apply to the im-
- 12 position of a civil monetary penalty under this section in
- 13 the same manner as such provisions apply with respect
- 14 to the imposition of a penalty under section 1128A of such
- 15 Act.
- 16 SEC. 153. ALTERNATIVE DISPUTE RESOLUTION.
- 17 (a) In General.—Not later than July 1, 1996, the
- 18 Secretary shall, by regulation, develop alternative dispute
- 19 resolution methods for use by individuals, health informa-
- 20 tion trustees, and other persons in resolving claims under
- 21 section 151.
- 22 (b) Effect on Initiation of Civil Actions.—
- 23 (1) IN GENERAL.—Subject to paragraph (2),
- the regulations established under subsection (a) may
- provide that an individual alleging that a right of

- the individual under this Act has been violated shall pursue at least one alternative dispute resolution method developed under such subsection as a condition precedent to commencing a civil action under section 151.
 - (2) LIMITATION.—Such regulations may not require an individual to refrain from commencing a civil action to pursue one or more alternative dispute resolution method for a period that is greater than 6 months.
 - (3) SUSPENSION OF STATUTE OF LIMITATIONS.—The regulations established by the Secretary under subsection (a) may provide that a period in which an individual described in paragraph (1) pursues (as defined by the Secretary) an alternative dispute resolution method under this section shall be excluded in computing the period of limitations under section 151(e).
- 19 (c) METHODS.—The methods under subsection (a) 20 shall include at least the following:
- 21 (1) Arbitration.—The use of arbitration.
- 22 (2) MEDIATION.—The use of mediation.
- 23 (3) EARLY OFFERS OF SETTLEMENT.—The use 24 of a process under which parties make early offers 25 of settlement.

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1	(d) Standards for Establishing Methods.—In
2	developing alternative dispute resolution methods under
3	subsection (a), the Secretary shall ensure that the meth-
4	ods promote the resolution of claims in a manner that—
5	(1) is affordable for the parties involved;
6	(2) provides for timely and fair resolution of
7	claims; and
8	(3) provides for reasonably convenient access to
9	dispute resolution for individuals.
10	SEC. 154. AMENDMENTS TO CRIMINAL LAW.
11	(a) IN GENERAL.—Title 18, United States Code, is
12	amended by inserting after chapter 89 the following:
	"
13	"CHAPTER 90—PROTECTED HEALTH
13 14	"CHAPTER 90—PROTECTED HEALTH INFORMATION
	"Sec. "1831. Definitions. "1832. Obtaining protected health information under false pretenses. "1833. Monetary gain from obtaining protected health information under false pretenses. "1834. Knowing and unlawful obtaining of protected health information. "1835. Monetary gain from knowing and unlawful obtaining of protected health information. "1836. Knowing and unlawful use or disclosure of protected health information. "1837. Monetary gain from knowing and unlawful sale, transfer, or use of pro-
114	"Sec. "1831. Definitions. "1832. Obtaining protected health information under false pretenses. "1833. Monetary gain from obtaining protected health information under false pretenses. "1834. Knowing and unlawful obtaining of protected health information. "1835. Monetary gain from knowing and unlawful obtaining of protected health information. "1836. Knowing and unlawful use or disclosure of protected health information. "1837. Monetary gain from knowing and unlawful sale, transfer, or use of protected health information.
114	"Sec. "1831. Definitions. "1832. Obtaining protected health information under false pretenses. "1833. Monetary gain from obtaining protected health information under false pretenses. "1834. Knowing and unlawful obtaining of protected health information. "1835. Monetary gain from knowing and unlawful obtaining of protected health information. "1836. Knowing and unlawful use or disclosure of protected health information. "1837. Monetary gain from knowing and unlawful sale, transfer, or use of protected health information. "\$ 1831. Definitions
14 15 16	"Sec. "1831. Definitions. "1832. Obtaining protected health information under false pretenses. "1833. Monetary gain from obtaining protected health information under false pretenses. "1834. Knowing and unlawful obtaining of protected health information. "1835. Monetary gain from knowing and unlawful obtaining of protected health information. "1836. Knowing and unlawful use or disclosure of protected health information. "1837. Monetary gain from knowing and unlawful sale, transfer, or use of protected health information. "\$ 1831. Definitions "As used in this chapter—

1	"(2) the term 'protected health information' has
2	the meaning given such term in section 3(a)(3) of
3	such Act; and
4	"(3) the term 'protected individual' has the
5	meaning given such term in section 3(a)(4) of such
6	Act.
7	"§ 1832. Obtaining protected health information
8	under false pretenses
9	"Whoever under false pretenses—
10	"(1) requests or obtains protected health infor-
11	mation from a health information trustee; or
12	"(2) obtains from a protected individual an au-
13	thorization for the disclosure of protected health in-
14	formation about the individual maintained by a
15	health information trustee;
16	shall be fined under this title or imprisoned not more than
17	5 years, or both.
18	"§ 1833. Monetary gain from obtaining protected
19	health information under false pretenses
20	"Whoever under false pretenses—
21	"(1) requests or obtains protected health infor-
22	mation from a health information trustee with the
23	intent to sell, transfer, or use such information for
24	profit or monetary gain; or

1	"(2) obtains from a protected individual an au-
2	thorization for the disclosure of protected health in-
3	formation about the individual maintained by a
4	health information trustee with the intent to sell,
5	transfer, or use such authorization for profit or
6	monetary gain;
7	and knowingly sells, transfers, or uses such information
8	or authorization for profit or monetary gain shall be fined
9	under this title or imprisoned not more than 10 years, or
10	both.
11	"§ 1834. Knowing and unlawful obtaining of pro-
12	tected health information
13	"Whoever knowingly obtains protected health infor-
14	mation from a health information trustee in violation of
15	the Fair Health Information Practices Act of 1995, know-
	the Fair Health Information Practices Act of 1995, knowing that such obtaining is unlawful, shall be fined under
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16 17	ing that such obtaining is unlawful, shall be fined under
16 17	ing that such obtaining is unlawful, shall be fined under this title or imprisoned not more than 5 years, or both.
16 17 18	ing that such obtaining is unlawful, shall be fined under this title or imprisoned not more than 5 years, or both. "§1835. Monetary gain from knowing and unlawful
16 17 18 19	ing that such obtaining is unlawful, shall be fined under this title or imprisoned not more than 5 years, or both. "§1835. Monetary gain from knowing and unlawful obtaining of protected health information
16 17 18 19 20	ing that such obtaining is unlawful, shall be fined under this title or imprisoned not more than 5 years, or both. "§1835. Monetary gain from knowing and unlawful obtaining of protected health information "Whoever knowingly—
16 17 18 19 20 21	ing that such obtaining is unlawful, shall be fined under this title or imprisoned not more than 5 years, or both. "§1835. Monetary gain from knowing and unlawful obtaining of protected health information "Whoever knowingly— "(1) obtains protected health information from

1	to sell, transfer, or use such information for profit
2	or monetary gain; and
3	"(2) knowingly sells, transfers, or uses such in-
4	formation for profit or monetary gain;
5	shall be fined under this title or imprisoned not more than
6	10 years, or both.
7	"§ 1836. Knowing and unlawful use or disclosure of
8	protected health information
9	"Whoever knowingly uses or discloses protected
10	health information in violation of the Fair Health Infor-
11	mation Practices Act of 1995, knowing that such use or
12	disclosure is unlawful, shall be fined under this title or
13	imprisoned not more than 5 years, or both.
14	"§ 1837. Monetary gain from knowing and unlawful
15	sale, transfer, or use of protected health
16	information
17	"Whoever knowingly sells, transfers, or uses pro-
18	tected health information in violation of the Fair Health
19	Information Practices Act of 1995, knowing that such
20	sale, transfer, or use is unlawful, shall be fined under this
21	title or imprisoned not more than 10 years, or both.".
22	(b) CLERICAL AMENDMENT.—The table of chapters
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	for part I of title 18, United States Code, is amended by
24	inserting after the item relating to chapter 89 the follow-
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1 TITLE II—AMENDMENTS TO 2 TITLE 5, UNITED STATES CODE

- 3 SEC. 201. AMENDMENTS TO TITLE 5, UNITED STATES CODE.
- 4 (a) New Subsection.—Section 552a of title 5,
- 5 United States Code, is amended by adding at the end the
- 6 following:
- 7 "(w) Medical Exemptions.—The head of an agen-
- 8 cy that is a health information trustee (as defined in sec-
- 9 tion 3(b)(6) of the Fair Health Information Practices Act
- 10 of 1995) shall promulgate rules, in accordance with the
- 11 requirements (including general notice) of subsections
- 12 (b)(1), (b)(2), (b)(3), (c), and (e) of section 553 of this
- 13 title, to exempt a system of records within the agency, to
- 14 the extent that the system of records contains protected
- 15 health information (as defined in section 3(a)(3) of such
- 16 Act), from all provisions of this section except subsections
- 17 (e)(1), (e)(2), subparagraphs (A) through (C) and (E)
- 18 through (I) of subsection (e)(4), and subsections (e)(5),
- 19 (e)(6), (e)(9), (e)(12), (l), (n), (o), (p), (q), (r), and (u).".
- 20 (b) Repeal.—Section 552a(f)(3) of title 5, United
- 21 States Code, is amended by striking "pertaining to him,"
- 22 and all that follows through the semicolon and inserting
- 23 "pertaining to the individual;".

1	TITLE III—REGULATIONS, RE-
2	SEARCH, AND EDUCATION;
3	EFFECTIVE DATES; APPLICA-
4	BILITY; AND RELATIONSHIP
5	TO OTHER LAWS
6	SEC. 301. REGULATIONS; RESEARCH AND EDUCATION.
7	(a) REGULATIONS.—Not later than July 1, 1996, the
8	Secretary shall prescribe regulations to carry out this Act
9	(b) Research and Technical Support.—The
10	Secretary may sponsor—
11	(1) research relating to the privacy and security
12	of protected health information;
13	(2) the development of consent forms governing
14	disclosure of such information; and
15	(3) the development of technology to implement
16	standards regarding such information.
17	(c) Education.—The Secretary shall establish edu-
18	cation and awareness programs—
19	(1) to foster adequate security practices by
20	health information trustees;
21	(2) to train personnel of health information
22	trustees respecting the duties of such personnel with
23	respect to protected health information; and

- 1 (3) to inform individuals and employers who 2 purchase health care respecting their rights with respect to such information. 3 SEC. 302. EFFECTIVE DATES. (a) IN GENERAL.—Except as provided in subsection 5 (b), this Act, and the amendments made by this Act, shall take effect on January 1, 1997. (b) Provisions Effective Immediately.—A pro-8 vision of this Act shall take effect on the date of the enactment of this Act if the provision— 10 11 (1) imposes a duty on the Secretary to develop, 12 establish, or promulgate regulations, guidelines, notices, statements, or education and awareness pro-13 14 grams; or (2) authorizes the Secretary to sponsor research 15 or the development of forms or technology. 16 SEC. 303. APPLICABILITY. (a) PROTECTED HEALTH INFORMATION.—Except as 18 provided in subsections (b) and (c), the provisions of this Act shall apply to any protected health information that is received, created, used, maintained, or disclosed by a health information trustee in a State on or after January 1, 1997, regardless of whether the information existed or 23
- 25 (b) Exception.—

was disclosed prior to such date.

1	(1) In general.—The provisions of this Act
2	shall not apply to a trustee described in paragraph
3	(2), except with respect to protected health informa-
4	tion that is received by the trustee on or after Janu-
5	ary 1, 1997.
6	(2) Applicability.—A trustee referred to in
7	paragraph (1) is—
8	(A) a health researcher; or
9	(B) a person who, with respect to specific
10	protected health information, received the infor-
11	mation—
12	(i) pursuant to—
13	(I) section 117 (relating to emer-
14	gency circumstances);
15	(II) section 118 (relating to judi-
16	cial and administrative purposes);
17	(III) section 119 (relating to law
18	enforcement); or
19	(IV) section 120 (relating to sub-
20	poenas, warrants, and search war-
21	rants); or
22	(ii) while acting in whole or in part in
23	the capacity of an officer or employee of a
24	person described in clause (i).

1	(c) Authorizations for Disclosures.—An au-
2	thorization for the disclosure of protected health informa-
3	tion about a protected individual that is executed by the
4	individual before January 1, 1997, and is recognized and
5	valid under State law on December 31, 1996, shall remain
6	valid and shall not be subject to the requirements of sec-
7	tion 112 until January 1, 1998, or the occurrence of the
8	date or event (if any) specified in the authorization upon
9	which the authorization expires, whichever occurs earlier.
10	SEC. 304. RELATIONSHIP TO OTHER LAWS.
11	(a) STATE LAW.—Except as otherwise provided in
12	subsections (b), (c), (d), and (f), a State may not estab-
13	lish, continue in effect, or enforce any State law to the
14	extent that the law is inconsistent with, or imposes addi-
15	tional requirements with respect to, any of the following:
16	(1) A duty of a health information trustee
17	under this Act.
18	(2) An authority of a health information trustee
19	under this Act to disclose protected health informa-
20	tion.
21	(3) A provision of subtitle C (relating to access
22	procedures and challenge rights), subtitle D (mis-
23	cellaneous provisions), or subtitle E (relating to en-
24	forcement).

- 1 (b) Laws Relating to Public Health and Men-
- 2 TAL HEALTH.—This Act does not preempt, supersede, or
- 3 modify the operation of any State law regarding public
- 4 health or mental health to the extent that the law prohibits
- 5 or regulates a disclosure of protected health information
- 6 that is permitted under this Act.
- 7 (c) Criminal Penalties.—A State may establish
- 8 and enforce criminal penalties with respect to a failure to
- 9 comply with a provision of this Act.
- 10 (d) Privileges.—A privilege that a person has
- 11 under law in a court of a State or the United States or
- 12 under the rules of any agency of a State or the United
- 13 States may not be diminished, waived, or otherwise af-
- 14 fected by—
- 15 (1) the execution by a protected individual of an
- authorization for disclosure of protected health in-
- formation under this Act, if the authorization is exe-
- cuted for the purpose of receiving health care or pro-
- viding for the payment for health care; or
- 20 (2) any provision of this Act that authorizes the
- 21 disclosure of protected health information for the
- purpose of receiving health care or providing for the
- payment for health care.
- 24 (e) DEPARTMENT OF VETERANS AFFAIRS.—The lim-
- 25 itations on use and disclosure of protected health informa-

tion under this Act shall not be construed to prevent any exchange of such information within and among components of the Department of Veterans Affairs that deter-4 mine eligibility for or entitlement to, or that provide, benefits under laws administered by the Secretary of Veterans Affairs. 6 (f) CERTAIN DUTIES UNDER STATE OR FEDERAL 7 Law.—This Act shall not be construed to preempt, super-8 sede, or modify the operation of any of the following: (1) Any law that provides for the reporting of 10 11 vital statistics such as birth or death information. 12 (2) Any law requiring the reporting of abuse or neglect information about any individual. 13 14 (3) Subpart II of part E of title XXVI of the 15 Public Health Service Act (relating to notifications 16 of emergency response employees of possible expo-17 sure to infectious diseases). 18 The Americans with Disabilities Act of 19 1990. 20 (5) Any Federal or State statute that establishes a privilege for records used in health profes-21 22 sional peer review activities. 23 (f) Secretarial Authority.— 24 (1) SECRETARY OF HEALTH AND HUMAN SERV-

ICES.—A provision of this Act does not preempt, su-

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persede, or modify the operation of section 543 of the Public Health Service Act, except to the extent that the Secretary of Health and Human Services determines through regulations promulgated by such Secretary that the provision provides greater protection for protected health information, and the rights of protected individuals, than is provided under such section 543.

(2) Secretary of Veterans Affairs.—A provision of this Act does not preempt, supersede, or modify the operation of section 7332 of title 38, United States Code, except to the extent that the Secretary of Veterans Affairs determines through regulations promulgated by such Secretary that the provision provides greater protection for protected health information, and the rights of protected individuals, than is provided under such section 7332.

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